

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK

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CHARLES WATSON,

Plaintiff,

v.

M.D. LESTER N. WRIGHT, et al.,

Defendants.

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**REPORT, RECOMMENDATION  
AND ORDER**

08-CV-00960(A)(M)

This case was referred to me by Hon. Richard J. Arcara for supervision of pretrial proceedings, including preparation of a report and recommendation on dispositive motions [36].<sup>1</sup> Before me are defendant Kathleen Sebelius' motion to dismiss the Third Amended Complaint [137] and plaintiff's motions for leave to file a Fourth Amended Complaint [153] and to transfer venue [109]. Oral argument as held on January 10, 2011 [176].

For the following reasons, I recommend that defendant Sebelius' motion to dismiss be granted and that plaintiff's motion for leave to amend be denied to the extent it seeks to assert an amended claim against defendant Sebelius, and I order that plaintiff's motion to amend be granted to the extent it seeks to add supplemental claims and that plaintiff's motion to transfer venue be granted in part and denied in part.

**BACKGROUND**

Plaintiff, an inmate, commenced this action *pro se* pursuant to 42 U.S.C. §1983, alleging that defendants have been deliberately indifferent to his medical needs while he has

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<sup>1</sup>

Bracketed references are to the CM/ECF docket entries.

been incarcerated by the New York State Department of Correctional Services (“DOCS”), that they prohibited him from participating in a clinical drug trial in violation of due process, and that they have retaliated against him. Third Amended Complaint [96]. Other than defendant Sebelius, the remaining defendants are all employed by DOCS (“State defendants”).

Defendant Sebelius moves to dismiss the Third Amended Complaint as against her [137]. In response to that motion, plaintiff moves for leave to file a Fourth Amended Complaint [153]. Plaintiff also moves to transfer venue of certain claims alleged in the Third Amended Complaint [109].<sup>2</sup>

## ANALYSIS

### A. Defendant Sebelius’ Motion to Dismiss/Plaintiff’s Motion for Leave to Amend

In response to defendant Sebelius’ motion to dismiss, plaintiff moves for leave to file a Fourth Amended Complaint. This motion is opposed by all defendants.

Leave to amend “should not be denied unless there is evidence of undue delay, bad faith, undue prejudice to the non-movant, or futility.” Milanese v. Rust-Oleum Corp., 244 F.3d 104, 110 (2d Cir.2001). “An amendment will be deemed futile, and the motion to amend denied, where the amendment would be subject to dismissal [under Fed. R. Civ. P. (“Rule”) 12(b)(6)] for failure to state a claim upon which relief may be granted.” Christian v. Town of Riga, 649 F.Supp.2d 84, 101 (W.D.N.Y. 2009) (Telesca, J.), reconsideration denied, 2010 WL 4116785.

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<sup>2</sup> I deferred setting a briefing schedule on plaintiff’s motion for a protective order [113] pending resolution of these motions. October 4, 2010 Text Order [150].

## **1. Defendant Sebelius' Opposition to Plaintiff's Motion for Leave to Amend**

The proposed Fourth Amended Complaint alleges that plaintiff suffers from Hepatitis C and that he suffers from liver disease as a result of this condition. Proposed Fourth Amended Complaint [153-1], ¶¶38-39. Plaintiff alleges that in October 2008 he became aware of a Hepatitis C clinical drug trial, but was advised by DOCS that inmates were not allowed to participate in such trials pursuant to DOCS Directive 403 and 45 CFR, part 46, subpart C. Id., ¶¶46-47.

Plaintiff alleges that defendant Sebelius in her capacity as the Secretary of the United States Department of Health and Human Services (“HHS”) is statutorily empowered to:

- 1) regulate clinical drug trials conducted by entities not funded or supported by HHS pursuant to 21 U.S.C. §393(d)(2)(C), but has never enacted rules “effectively banning the use of prisoners in clinical drug trials by private entities” id., ¶48; and
- 2) “encourage and fund research . . . studies in the health sciences related to the . . . prevention of humans diseases and disorders” pursuant to 42 U.S.C. §241(a) and 284(b)(1)(A)(ii), and has instituted rules (45 CFR part 46, subpart C) “concerning the participation of prisoners in clinical trials supported by HHS”. Id., ¶¶49-50.

According to plaintiff, “[t]he failure of defendant Sebelius to encourage, fund and support the participation of prisoners in clinical drug trials of Hepatitis C treatment and the propagation of regulation which effectively bans the participation of prisoners in non-HHS funded clinical trials constitutes a violation of federal statute and of the Equal protection and Substantive Due Process components of the Fifth Amendment”. Id., ¶67, Sixth Cause of Action. Plaintiff seeks an injunction requiring defendant Sebelius “to follow [her] statutory

dictates and facilitate the opportunity for prisoners to apply to participate in therapeutic clinical drug trials for the treatment of Hepatitis C”, and a declaratory judgment against defendant Sebelius “affirming the Plaintiff’s right, even as a prisoner, to participate in a clinical drug trial for therapeutic treatment of his ailment”. Id., Wherefore Clause, ¶¶A(5) and B. Plaintiff’s claims for injunctive and declaratory relief are brought pursuant to 28 U.S.C. §1331(Mandamus Act) and §2201 (Declaratory Judgment Act). Proposed Fourth Amended Complaint [153-1], p. 2 and ¶1.

**a. Plaintiff’s Standing**

Defendant Sebelius argues that “[p]laintiff has not asserted an immediate or real threat of future harm; therefore, plaintiff does not have standing to seek this broad injunctive relief as the court can only impose remedies that benefit the parties before the court”. Defendant Sebelius’ Memorandum of Law [164], p. 11.

To establish standing “a plaintiff must demonstrate that (1) he or she has suffered an injury; (2) the injury is traceable to the defendants’ conduct; and (3) a federal court decision is likely to redress the injury.” Deshawn E. by Charlotte E. v. Safir, 156 F.3d 340, 344 (2d Cir. 1998). “A plaintiff seeking injunctive or declaratory relief cannot rely on *past* injury to satisfy the injury requirement but must show a likelihood that he or she will be injured in the future.” Id. (emphasis added)

Without identifying any current Hepatitis C clinical drug trials he would qualify for, plaintiff’s proposed Fourth Amended Complaint seeks prospective relief to facilitate prisoner participation in clinical drug trials for the treatment of Hepatitis C. Plaintiff having

failed to identify any current or future Hepatitis C clinical drug trial for which he would qualify, I find that plaintiff has not sufficiently alleged the likelihood of future harm. In fact, plaintiff's Third Amended Complaint concedes that "there are no trials planned with participation of prisoners". Third Amended Complaint [96], ¶46. I also find that plaintiff has not established standing to seek relief on behalf of other prisoners as alleged in his proposed Fourth Amended Complaint.

**b. Futility of the Proposed Amendment**

Even assuming that plaintiff had established standing to assert his claims against defendant Sebelius, I conclude that it would be futile to permit the amendment. Defendant Sebelius argues that: 1) plaintiff's claims are barred by sovereign immunity (defendant Sebelius' Memorandum of Law [138], pp. 9-12); 2) even if the clinical drug trials referenced by plaintiff were funded or conducted by HHS, defendant Sebelius does not have the authority to provide the relief plaintiff requests (*id.*, pp. 7-12); 3) the absence of regulations do not deny prisoners the opportunity to participate in privately sponsored FDA clinical drug trials (*id.*, pp. 12-13); and 4) plaintiff cannot meet his burden of establishing his entitlement to mandamus relief. *Id.*, pp. 13-14. I will address these arguments individually.

Defendant Sebelius argues that plaintiff's motion should be denied "because the federal defendant has not waived sovereign immunity with respect to plaintiff's equal protection

and substantive due process claims". Defendant Sebelius' Memorandum of Law [164], p. 6.<sup>3</sup> I disagree.

"Sovereign immunity is a jurisdictional bar . . . which, absent a waiver, shields the federal government, its agencies and its officers acting in their official capacity from suits seeking monetary damages." Rosales v. United States Postal Service, 2010 WL 2653381, \*2 (E.D.N.Y. 2010) (emphasis added).<sup>4</sup> Unlike the Third Amended Complaint ([96], p. 2), the proposed Fourth Amended Complaint ([153], p. 2) seeks *no* monetary damages against defendant Sebelius, and does not seek relief against her under 42 U.S.C. §1983 or Bivens v. Six Unknown Agents, 403 U.S. 388 (1971). Therefore, I find that plaintiff's claims in the proposed Fourth Amended Complaint are not barred by sovereign immunity. Nevertheless, I find that the proposed Fourth Amended Complaint fails, as a matter of law, to state a claim against defendant Sebelius.

Petitioner relies on 42 U.S.C. §§241(a) and 284(b) in support of his claim against defendant Sebelius. However, neither statute grants plaintiff the right to participate in a clinical

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<sup>3</sup> In opposition to plaintiff's Third Amended Complaint defendant Sebelius similarly argues that plaintiff's 42 U.S.C. §1983 claims for monetary relief must be dismissed on the grounds of sovereign immunity. Defendant Sebelius' Memorandum of Law [138], pp. 9-12.

<sup>4</sup> The Administrative Procedure Act ("APA") provides that "[a]n action in a court of the United States seeking relief *other than money damages* and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party." 5 U.S.C. §702 (emphasis added). Although the APA is not cited in plaintiff's proposed Fourth Amended Complaint, the APA "does not provide an independent basis of jurisdiction to review agency actions." Assiniboine and Sioux Tribes of Fort Peck Indian Reservation v. Board of Oil and Gas Conservation of State of Montana, 792 F.2d 782, 793 (9th Cir. 1986).

drug trial. According to 42 U.S.C. §241(a), defendant Sebelius, as Secretary of HHS, is required to “conduct, . . . encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man”. 42 U.S.C. §284(b)(1)(A)(ii) similarly provides that “[i]n carrying out the purposes of section 241 . . . the Secretary, acting through the Director of each national research institute . . . shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to . . . the detection, diagnosis, treatment, and prevention of human diseases and disorders”.

Moreover, the regulations governing research conducted or supported by HHS involving prisoners as subjects (45 C.F.R. §§301 - 306) expressly recognize that HHS’ authority to authorize research involving prisoners as subjects does not preempt state and local laws barring such activity. 45 C.F.R. §46.301(b). Thus, it is apparent that the statutory and regulatory authority upon which plaintiff relies does not grant plaintiff the legal right to participate in a clinical trial, and does not afford the Secretary the power to facilitate or encourage the participation of plaintiff in a clinical drug trial. Defendant Sebelius’ Memorandum of Law [164], p. 9. Because “a claim for injunctive relief can stand only against someone who has the authority to grant it”, Williams v. Doyle, 494 F.Supp.2d 1019, 1024 (W.D.Wis. 2007), I find that the proposed amendment would be futile.

To the extent plaintiff is basing his claim on the alleged failure of defendant Sebelius to enact regulations governing prisoner participation in privately sponsored clinical

drug trials, such claim is likewise futile. As defendant Sebelius argues, the lack of regulation with respect to prisoner participation in privately sponsored clinical drug trials “arguably would make it more administratively simple to enroll a prisoner in a privately sponsored clinical drug trial, as no additional constraints on ethical review and approval of the clinical trial - such as those imposed by Subpart C - would apply”. Defendant Sebelius’ Memorandum of Law [164], pp. 12-13.

Even assuming that plaintiff could establish that defendant Sebelius had authority to permit him to participate in a clinical drug trial (whether HHS or privately sponsored), he has not established his entitlement to mandamus relief. A writ of mandamus may issue only when there is: “(1) a clear right in the plaintiff to the relief sought; (2) a plainly defined and peremptory duty on the defendant's part to do the act in question; and (3) lack of another available, adequate remedy.” Billiteri v. United States Board of Parole, 541 F.2d 938, 946 (2d Cir.1976). “[J]urisdiction under the mandamus statute is limited to actions seeking to compel the performance of a nondiscretionary duty.” Duamutef v. Immigration and Naturalization Service, 386 F.3d 172, 180 (2d Cir. 2004). Having failed to establish neither a clear entitlement to participation in a clinical drug trial nor a non-discretionary duty on the part of defendant Sebelius to facilitate his participation, plaintiff has not established his entitlement to mandamus relief.

## **2. State Defendants’ Opposition to Plaintiff’s Motion for Leave to Amend**

Although plaintiff sought leave to file the proposed Fourth Amended Complaint in an attempt to correct the deficiencies raised by defendant Sebelius’ motion to dismiss, the

proposed Fourth Amended Complaint also adds allegations against the State defendants. The State defendants oppose plaintiff's motion for leave to amend, arguing that this amendment is barred by the Case Management Order deadline for amending pleadings<sup>5</sup> and that the amendments are otherwise futile. State Defendants' Memorandum of Law [163], Points I and II. I disagree.

The initial Case Management Order, which was issued when plaintiff's Second Amended Complaint [45] was the operative pleading, required all motions to amend to be filed by July 24, 2009. [72], ¶2. This deadline was not extended in the Amended Case Management Order [93].<sup>6</sup>

Ordinarily, “[a] party seeking to amend a pleading after the date specified in a scheduling order must first show ‘good cause’ for the amendment under Rule 16(b); then, if good cause can be shown, the party must demonstrate that the amendment is proper under Rule 15(a).” Carnrite v. Granada Hospital Group, Inc., 175 F.R.D. 439, 446 (W.D.N.Y. 1997) (Arcara, J.); Parker v. Columbia Pictures Industries, 204 F.3d 326, 340 (2d Cir. 2000) (“despite the lenient standard of Rule 15(a), a district court does not abuse its discretion in denying leave to amend the pleadings after the deadlines set in the scheduling order where the moving party has failed to establish good cause”). While plaintiff's motion is characterized as a motion to amend, what plaintiff actually seeks is to *supplement* his Third Amended Complaint with the alleged acts of deliberate indifference occurring *since* the filing of that pleading pursuant to Rule

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<sup>5</sup> Defendant Sebelius did not raise this argument.

<sup>6</sup> Although plaintiff was granted leave to file a Third Amended Complaint [96], this was based upon the lack of opposition by defendants. February 23, 2010 Text Order [95].

15(d). Plaintiff's Reply [170], p. 1 ("The amended complaint was also submitted pursuant to [Rule] 15(d) to bring events to the Court's attention since the filing of the Third Amended Complaint").

Under these circumstances, Rule 16(b)'s good cause standard is not applicable.

*See Ohio Valley Environmental Coalition v. United States Army Corps of Engineers*, 243 F.R.D. 253, 256 (S.D.W.Va. 2007).<sup>7</sup> The Case Management Order set a deadline for "amending" pleadings, but not for supplementation. [72], ¶2. "Unlike motions to amend . . . Rule 16's plain language does not require courts to set a deadline for filing a motion to supplement and the parties in this case did not set such a deadline in their Scheduling Order." *Fremont Investment & Loan v. Beckley Singleton, Chtd.*, 2007 WL 1213677, \*7 (D.Nev. 2007).

The Fourth Amended Complaint adds allegations that plaintiff has not been referred to a dermatologist for his pruritus and that he requires additional showers and lotion for this condition. Proposed Fourth Amended Complaint [153-1], ¶43. It also adds allegations that plaintiff's prescription for Ensure was discontinued, and requests a change of his primary care provider. *Id.*, ¶¶44-45.

My previous decisions on plaintiff's motions for preliminary injunctions concluded that plaintiff had not established the likelihood of success on the merits of his

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<sup>7</sup> Compare with *McGrotha v. Fed Ex Ground Package System, Inc.*, 2007 WL 640457, \*2 (M.D.Ga. 2007) ("When a motion to supplement is filed after the scheduling order's deadline, however, a party must first demonstrate good cause under Rule 16(b) before a court can consider whether supplementation is proper under Rule 15(d)").

deliberate indifference claims alleged in his earlier complaints. *See, e.g.*, June 8, 2009 Report, Recommendation and Order [70]; March 10, 2010 Report and Recommendation [98]. However, the issue of futility under the Rule 12 standard is distinct from the likelihood of success standard applied in the preliminary injunction context.

“[I]t must be remembered that the question on a 12(b)(6) motion ‘is not whether a plaintiff is likely to prevail ultimately, but whether the claimant is entitled to offer evidence to support the claims . . . [even where] recovery is very remote and unlikely’”. Cole v. Artuz, 2000 WL 760749, \*5 (S.D.N.Y. 2000) (*quoting Chance v. Armstrong*, 143 F.3d 698, 701 (2d Cir. 1998)). Applying this standard, I do not find that the supplemental allegations of deliberate indifference in the proposed Fourth Amended Complaint fail, as a matter of law, to state a claim. Although defendants challenge each supplemental act of deliberate indifference asserted in the proposed Fourth Amended Complaint individually, “[t]he *totality* of an inmate’s medical care must be considered in order to determine whether a prison official has acted with deliberate indifference to serious medical needs.” Wandell v. Koenigsmann, 2000 WL 1036030, \*3 (S.D.N.Y. 2000) (emphasis added). Thus, while each supplemental act standing alone may not demonstrate deliberate indifference, when analyzed collectively and in conjunction with the totality of plaintiff’s medical care, the proposed Fourth Amended Complaint may adequately state a deliberate indifference claim sufficient to survive dismissal.

Therefore, I order that plaintiff’s motion for leave to amend be granted to the extent it seeks to add supplemental claims against the State defendants, but otherwise

recommend that it be denied.<sup>8</sup> Since plaintiff has failed to offer any opposition to defendant Sebelius' motion to dismiss, other than seeking to amend, I recommend that defendant Sebelius' motion to dismiss be granted. *See Bankruptcy Trust of Gerard Sillam v. Refco Group, LLC*, 2006 WL 2129786,\* 4 (S.D.N.Y. 2006) ("Essentially, plaintiffs consent to the dismissal of the present complaint, but seek leave to amend the complaint under Fed.R.Civ.P. 15(a)").

#### **B. Plaintiff's Motion to Transfer Venue<sup>9</sup>**

Plaintiff moves to transfer the Sixth Cause of Action alleging a retaliatory transfer by officials at DOCS' central office and Green Haven Correctional Facility to the Southern District of New York. Plaintiff's Motion to Transfer Venue [109], p. 2. Because the State defendants do not oppose this aspect of plaintiff's motion, *see* State Defendants' Memorandum of Law [155], p. 4, I order that it be granted.

Plaintiff also moves to transfer his Fifth Cause of Action against defendants Sebelius and Wright challenging the policy of prohibiting prisoners from participating in clinical

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<sup>8</sup> "Although the Court of Appeals for the Second Circuit has not ruled on whether a motion to amend a pleading is properly classified as dispositive or nondispositive, the weight of authority within this Circuit classifies a motion to amend a pleading as a non-dispositive pre-trial motion." *Smith v. Goord*, 2007 WL 496371, \*2 (W.D.N.Y. 2007) (Siragusa, J.). *See Fielding v. Tollaksen*, 510 F.3d 175, 178 (2d Cir. 2007) ("On the other hand, some district courts in this circuit have held that a denial of a motion to amend is dispositive in situations where the denial is based on futility, because such a motion is analyzed under the same standard as a motion to dismiss for failure to state a claim or a motion for summary judgment, both of which are dispositive motions.") *Children First Foundation, Inc. v. Martinez*, 2007 WL 4618524, \*4 (N.D.N.Y. 2007). Therefore, erring on the side of caution, I will treat the motion to amend as dispositive to the extent that I am denying it on futility grounds. However, to the extent the motion seeks to supplement the claims against the State defendants, it is non-dispositive. *See Sidari v. Orleans County*, 169 F. Supp. 2d 158, 163 (W.D.N.Y. 2000) (Siragusa, J./Scott, M.J.).

<sup>9</sup> Motions to transfer venue are non-dispositive. *See Anscombe Broadcasting Group, Ltd. v. RJM Communications, Inc.*, 2004 WL 2491641, \*1 n.1 (W.D.N.Y. 2004) (Foschio, M.J.); *O'Brien v. Gold Star Technologies, Inc.*, 812 F. Supp. 383 (W.D.N.Y. 1993) (Heckman, M.J.).

drug trials to the District of Columbia. Plaintiff's Motion to Transfer Venue [109], p. 2. 28 U.S.C. §1391(b) provides that venue is proper in "(1) a judicial district where any defendant resides, if all defendants reside in the same State, (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (3) a judicial district in which any defendant may be found, if there is no district in which the action may otherwise be brought."

Since I am recommending that plaintiff's claims against defendant Sebelius - the only defendant with a connection to the District of Columbia - be dismissed, venue for the Fifth Cause of Action is not proper in the District of Columbia, because the operative facts against defendant Wright have no connection to that venue. Therefore, this aspect of plaintiff's motion to transfer venue is denied.

## **CONCLUSION**

For these reasons, I recommend that defendant Sebelius' motion to dismiss [137] be granted and that plaintiff's motion for leave to amend [153] be denied to the extent it seeks to assert an amended claim against defendant Sebelius, and I order that plaintiff's motion to amend [153] be granted to the extent it seeks to add supplemental claims against the State defendants and that plaintiff's motion to transfer venue [109] be granted to the extent it seeks to transfer the Sixth Cause of Action of the Third Amended Complaint ([96], ¶62) to the Southern District of New York, but otherwise is denied.

Unless otherwise ordered by Judge Arcara, any objections to this Report, Recommendation and Order must be filed with the clerk of this court by January 28, 2011

(applying the time frames set forth in Rules 6(a)(1)(C), 6(d), and 72(b)(2)). Any requests for extension of this deadline must be made to Judge Arcara. A party who “fails to object timely . . . . waives any right to further judicial review of [this] decision”. Wesolek v. Canadair Ltd., 838 F. 2d 55, 58 (2d Cir. 1988); Thomas v. Arn, 474 U.S. 140, 155 (1985).

Moreover, the district judge will ordinarily refuse to consider *de novo* arguments, case law and/or evidentiary material which could have been, but were not, presented to the magistrate judge in the first instance. Patterson-Leitch Co. v. Massachusetts Municipal Wholesale Electric Co., 840 F. 2d 985, 990-91 (1st Cir. 1988).

The parties are reminded that, pursuant to Rule 72(b) of the Local Rules of Civil Procedure for the Western District of New York, written objections “shall specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for each objection, and shall be supported by legal authority.” Failure to comply with the provisions of Local Rule 72(b), may result in the district judge’s refusal to consider the objection.

**SO ORDERED.**

DATED: January 11, 2011

/s/ Jeremiah J. McCarthy  
JEREMIAH J. MCCARTHY  
United States Magistrate Judge